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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,606	05/08/2001	Rubinah K. Chowdhary	273012011700	4962

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/851,606

Applicant(s)

CHOWDHARY ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

The amendment dated 2-22-05 is acknowledged.

Claims included in the prosecution are 1-28 and 30.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-28 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amends claims 1 and 4 to read, "upon hydration with an aqueous medium, said complex is " and then recites as Markush members, micelles, vesicles, emulsion and gel. It is unclear as to how just a hydration of the powder would result in different products claimed. One can understand hydration resulting one specific product. Steps leading to the formation of different products are missing in the claim.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 4-7, 16-18, 26-28 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,693,093. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in instant application and the patented claims (1-12) are drawn to the same method of preparation of the photosensitizer composition. Patented claims are generic with respect to the photosensitizer and the block polymer and therefore, instant species of 'polypyrrolic macrocyclic photosensitizer' and 'triblock polymer are deemed to be anticipated by the genus in the patented claims. Although patented independent claim 1 does not recite a solid support as recited in instant claims, since the patented claims recite 'comprising' it would be obvious to one of ordinary skill in the art such a support could be used in the method as also obvious from the patented dependent claim 10 which recites a solid support. With regard to claim 30: both patented claim and instant claim 30 are drawn to the same method of conducting photodynamic therapy using the hydrated complex and these are dependent claims and therefore, the same rationale is applicable.

#### Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider (6,258,378) by itself or in combination with Lyons (5,616,342) and Young (6,375,930).

Schneider discloses formulations containing liposomes and an active agent (diagnostic and therapeutic agents) in combination with polymers such as Pluronic F-108 and poloxamer. The method of preparation involves mixing the active agent with the emulsifying agent, poloxamer or Pluronic F-108 and the phospholipids such that the emulsifying agent is inside and outside the liposomes. The compositions are in a dried form and contain cryoprotectant such as sucrose (endo and exo-support) (abstract, col. 2, line 50 through col. 6, line 7, col. 7, lines 1-4 and 51-56, Examples and claims). What is lacking in Schneider is the teaching that the therapeutic agent or the diagnostic agent be a photosensitizer. However, it would have been obvious to one of ordinary skill in the art to encapsulate any active agent including a photosensitizer, with a reasonable expectation of success since Schneider teaches general applicability of the system to any agent and provides guidance to one of ordinary skill in the art.

Lyons discloses emulsion formulations containing photosensitizers such as claimed texaphyrins and sapphyrins and block copolymers such as poloxamers (abstract, col. 3, line 10 through col. 8, line 22 and claims).

Young discloses that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes (abstract, col. 11, line 33 through col. 13, line 43).

One of ordinary skill in the art would be further motivated to use Schneider's composition to deliver a photosensitizer since the references of Lyons, and Young show the routine practice in the art of the use of poloxamers containing emulsion systems, micelles and liposomes for the delivery of photosensitizers.

Note: The methodology used by Schneider in 6,258,378 for preparing the dried powder in the presence of sucrose is disclosed in Schneider (4,29, 360), which has been cited of interest before (note abstract, col. 2, line 18).

5. Claims 1-10, 16-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (5,616,342) in combination with Klaveness (5,674,468), See (6,015,576) individually or in combination.

Lyons as pointed out above, discloses emulsion formulations containing photosensitizers and poloxamer or Pluronic F 127 (abstract, col. 4, lines 44-65 and Example 1). What is lacking in McCarty is the teaching of the preparation of the composition in a dried form in the presence of solid supports such as lactose.

Kloveness while disclosing emulsion formulations containing Pluronics teaches that the emulsions can be lyophilized in the presence of lactose to prepare dried forms (col. 40, lines 28-45).

See teaches that emulsions can be lyophilized in the presence of cryopreservatives such as lactose to stabilize the emulsions and the contents (abstract, col. 6, line 57 through col. 7, line 8).

To prepare the emulsion of Lyons in a dry form using lactose as the solid support would have been obvious to one of ordinary skill in the art since such a procedure would stabilize the composition as taught by Kloveness, and See.

6. Claims 1-10, 16-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (5,616,342) in view of either Desai (6,074,666) or Madden (5,389,378) in further combination with Unger (6,028,066).

The teachings of Lyons have been discussed above. What are lacking in McCarty are the teachings of the preparation of the composition in a dried form in the presence of solid supports such as lactose and the use of claimed photosensitizers.

Desai discloses a method of preparation of lyophilized powders containing a phospholipid, a benzoporphyrins and lactose (endosupport) for photodynamic therapy (note columns 6-7, Examples and claims, claim 8 in particular).

Madden discloses a method of preparation of lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note Examples). The formulations are enclosed in a capsule (exo-support).

Unger while disclosing the formulations containing liposomes and micelles for therapeutic and diagnostic purposes teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of

lyophilization, additives such as glucose and trehalose are added (note the abstract, col. 4, lines 9-58 and col. 79, lines 45-57).

To include sugars such as lactose and trehalose and lyophilize the preparations of Lyons would have been obvious to one of ordinary skill in the art because Unger teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose and polymers such as PEG and polyvinyl pyrrolidone are added; the inclusion of sugars would have also have been obvious to one of ordinary skill in the art since these are protective agents according to Madden and these are routinely added in freeze dried preparations containing photosensitizers according to Desai.


The references of Heller (5,939,453) and Tachibana (6,176,842) are cited as interest.

Applicant's arguments have been fully considered, but are deemed to be moot in view of these new rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1615

GSK